

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Thomas Cunningham on 07/29/2010 and 08/19/2010 (for the changes made in the abstract). Claims 1-20 are allowed.

Please amend the abstract by consolidating 2 paragraphs into a single paragraph.

Please amend the claims as they appear below:

1. (Currently Amended): An isolated or purified *Bacillus* bacterium comprising:
a polynucleotide promoter sequence recognized and transcribed specifically during a sporulation stage, and
a polynucleotide that encodes a SigA polypeptide having the amino acid sequence of SEQ ID NO: 1 or a polypeptide that is at least ~~[[70%]]~~ 80% homologous to the amino acid sequence of SEQ ID NO: 1~~[[,]]~~ and which participates in transcription of a gene which is essential for growth during the vegetative growth period of said *Bacillus* bacterium.

wherein the promoter sequence is located ~~in a region of~~ between 1 to 198 bp upstream of, and operatively-linked to, said polynucleotide encoding *sigA*; and

Art Unit: 1656

wherein the promoter sequence is selected from the group consisting of a promoter sequence for expressing *sigH* gene of *Bacillus* and a promoter sequence for expressing *spolIA* operon of *Bacillus*.

2. (Currently Amended): The isolated or purified *Bacillus* bacterium, wherein the promoter sequence is selected from the group consisting of a promoter sequence for expressing *sigH* gene of *Bacillus* that contains the nucleotide sequence ranging from base numbers 987 to 1,027 of SEQ ID NO: 2, and a promoter sequence for expressing *spolIA* operon of *Bacillus* that contains a nucleotide sequence ranging from base numbers 1,081 to 1,110 of SEQ ID NO: 3.

3. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1 which is *Bacillus subtilis*.

4. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, further comprising a heterologous polynucleotide encoding a protein or polypeptide.

5. (Rejoined): A method for producing a protein or a polypeptide comprising expressing a heterologous polynucleotide in the *Bacillus* bacterium of claim 4, and recovering said protein or polypeptide.

6. (Rejoined): The method of claim 5, wherein the protein or polypeptide is a cellulase, amylase, or protease.

7. (Rejoined): The method of claim 5, wherein the protein or polypeptide comprises an amino acid sequence that is at least 70% homologous to SEQ ID NO: 4.

8. (Rejoined): The method of claim 5, wherein the protein or polypeptide comprises an amino acid sequence that is at least 70% homologous to SEQ ID NO: 19.

Art Unit: 1656

9. (Rejoined): The method of claim 5, wherein the protein or polypeptide comprises an amino acid sequence that is at least 70% homologous to SEQ ID NO: 21.

10. (Currently Amended): A method for constructing the *Bacillus* bacterium of claim 1 comprising:

transforming a *Bacillus* bacterium with a polynucleotide comprising a promoter sequence recognized and transcribed specifically during a sporulation stage, a polynucleotide that encodes a SigA polypeptide having the amino acid sequence of SEQ ID NO: 1 or a polypeptide that is at least ~~[[70%]]~~ 80% homologous to the amino acid sequence of SEQ ID NO: 1~~[[,]]~~ and which participates in transcription of a gene which is essential for growth during the vegetative growth period of said *Bacillus* bacterium.

wherein the promoter sequence is located ~~in a region of~~ between 1 to 198 bp upstream of, and operatively-linked to, said polynucleotide encoding *sigA*; and wherein the promoter sequence is selected from the group consisting of a promoter sequence for expressing *sigH* gene of *Bacillus* that contains the nucleotide sequence ~~ranging~~ from base numbers 987 to 1,027 of SEQ ID NO: 2, and a promoter sequence for expressing *spoIIA* operon of *Bacillus* that contains a nucleotide sequence ~~ranging~~ from base numbers 1,081 to 1,110 of SEQ ID NO: 3.

11. (Currently Amended): The method of claim 10, wherein said promoter sequence is one for expressing *sigH* gene of *Bacillus* that contains the nucleotide sequence ~~ranging~~ from base numbers 987 to 1,027 of SEQ ID NO: 2.

12. (Currently Amended): The method of claim 10, wherein said promoter sequence is one for expressing *spoIIA* operon of *Bacillus* that contains a nucleotide sequence ~~ranging~~ from base numbers 1,081 to 1,110 of SEQ ID NO: 3.

13. (Currently Amended): The method of claim 10, wherein said *sigA* gene encodes ~~[[a]]~~ the polypeptide comprising SEQ ID NO: 1.

Art Unit: 1656

14. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, which has the promoter sequence and the polynucleotide encoding SigA protein integrated into its genomic DNA.

15. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, wherein said *Bacillus* has the promoter sequence and the polynucleotide encoding SigA protein located on a plasmid.

16. (Currently Amended): The isolated or purified *Bacillus* bacterium of claim 1, wherein said *sigA* gene encodes ~~[[a]]~~ the polypeptide comprising SEQ ID NO: 1.

17. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, further comprising a heterologous polynucleotide encoding a protein or polypeptide.

18. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, further comprising a heterologous polynucleotide encoding a protein or polypeptide that is at least 70% homologous to the amino acid sequence of SEQ ID NO: 4.

19. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, further comprising a heterologous polynucleotide encoding a protein or polypeptide that is at least 70% homologous to the amino acid sequence of SEQ ID NO: 19.

20. (Previously Presented): The isolated or purified *Bacillus* bacterium of claim 1, further comprising a heterologous polynucleotide encoding a protein or polypeptide that is at least 70% homologous to the amino acid sequence of SEQ ID NO: 21.

21. (Cancelled): ~~The isolated or purified *Bacillus* bacterium of claim 1, wherein the polypeptide is at least 70% homologous to the amino acid sequence of SEQ ID NO:~~

Art Unit: 1656

~~1 and which participates in transcription of a gene which is essential for growth during the vegetative growth period of said *Bacillus* bacterium.~~

Claims 1-4 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 5-9, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 10/13/2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

REASONS FOR ALLOWANCE

The following is an Examiner's statement of reasons for allowance. While Hicks et al. ("Altering the level and regulation of the major sigma subunit of RNA polymerase

Art Unit: 1656

affects gene expression and development in *Bacillus subtilis*", Molecular Microbiology, Vol. 20, No. 1, XP002940914, 1996, Pages 201- 212, see IDS) teach a wild-type *Bacillus subtilis* strains (JH642b and KH441c) and mutant *Bacillus subtilis* strains (KH311 b and KH516c), wherein said mutant strains comprise, on their genome or plasmid, DNA having IPTG-inducible promoter Pspac recognized and transcribed specifically during the sporulation stage, and a *sigA* gene, the promoter sequences being ligated to an upstream end of *sigA* gene, the Examiner has found no teaching or suggestion in the prior art directed to an isolated or purified *Bacillus* bacterium comprising: a polynucleotide promoter sequence recognized and transcribed specifically during a sporulation stage, and a polynucleotide that encodes a SigA polypeptide having the amino acid sequence of SEQ ID NO: 1 or a polypeptide that is at least 80% homologous to the amino acid sequence of SEQ ID NO: 1 and which participates in transcription of a gene which is essential for growth during the vegetative growth period of said *Bacillus* bacterium, wherein the promoter sequence is located in a region of between 1 to 198 bp upstream of, and operatively-linked to, said polynucleotide encoding *sigA*; and wherein the promoter sequence is selected from the group consisting of a promoter sequence for expressing *sigH* gene of *Bacillus* and a promoter sequence for expressing *spoIIA* operon of *Bacillus*. It is noted by the Examiner that the claimed invention does not read on the naturally occurring *Bacillus subtilis* bacterium because promoter sequences upstream of *sigA* gene is separated by *dnaG* gene (1809 bp long) which encodes a DNA primase as evidenced by Hicks et al. (see Figure 1 on

Art Unit: 1656

page 202). Therefore, the claimed invention is novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached between 9:00 to 5:30 on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/590,275
Art Unit: 1656

Page 9

/JAE W LEE/
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656